PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

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PCT	То:			
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24			
	Arlington, VA 22202			
Date of mailing:	T ETATS-UNIS D'AMERIQUE			
29 March 2001 (29.03.01)	in its capacity as elected Office			
International application No.: PCT/DK00/00517	Applicant's or agent's file reference: 19536			
International filing date:	Priority date:			
19 September 2000 (19.09.00)	21 September 1999 (21.09.99)			
Applicant: MERRILD, Bente, Käthe, Yonne et al				
1. The designated Office is hereby notified of its election made: X In the demand filed with the International preliminary Examining Authority on: 25 January 2001 (25.01.01) In a notice effecting later election filed with the International Bureau on: 2. The election X was was not made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).				
The International Bureau of WIPO	Authorized officer:			
34, chemin des Colombettes 1211 Geneva 20, Switzerland	, T abas			
	l Zahra			

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INTERNATIONAL SEARCH REPORT

International application No.

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A. CLAS	SIFICATION OF SUBJECT MATTER				
IPC7:	IPC7: A61F 13/06 According to International Patent Classification (IPC) or to both national classification and IPC				
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Minimum 4	ocumentation searched (classification system followed b), cjanzilecznicu skupnje)		•	
IPC7:	A61F		<u></u>		
Documents	tion susrehed other than minimum documentation to th	e extent that such documen	nts are included in	the fields searched	
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Electronic	ata base consulted during the international search (num	e of data base and, where p	nrausicabje, acapsi	terms used)	
c. Doct	MENTS CONSIDERED TO BE RELEVANT			•	
Category*	Citation of document, with indication, where ap	propriate, of the relevan	n passages	Relevant to claim No.	
A	US 5497789 A (ZOOK), 12 March 1 abstract	996 (12.03.96),		1-10	
A	FR 1176074 B1 (JUAN LESIUK), 3 (03.04.59), figures 5,6, c1		1-10		
					
A	A JP 9099004 A (CHOYO KK)1997-07-15 (abstract) World P atents Index (oneline). London, U.k:Derwent Publicat ions, Ltd: (retrieved on 2000-12-14).Retrieved from; EPO WPI Database. DW199725, Accession No.98-149073;				
A	SE 464906 B (AB IE-KLINIKEN), 1 (01.07.91), figure 1, abstra	1-10			
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"A" docume	categories of cited documents: nt defining the general state of the art which is not convidered	date and test in one	illice with the applic	macional filing date or princity adva but cited to understand nyention	
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"P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family.					
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INTERNATIONAL SEARCH REPORT

International application No.
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Unitno)	ation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Caugary'	Citation of document, with indication, where appropriate, of the rele	want passages	Relevant to claim Ne
A	US 5823195 A (SHOOK ET AL), 20 October 1998 (20.10.98), abstract		1-10
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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	ent document n scarch report		Publication date	* Paient family member(s)	Publication date
20	5497789	A	12/03/96	NONE	
FR	1176074	81	03/04/59	NONE	
SE	464906	В	01/07/91	SE 8903007 A	14/03/91
US	5823195	A	20/10/98	NONE	· · · · · · · · · · · · · · · · · · ·

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21 September 1999 (21.09.1999) Dk

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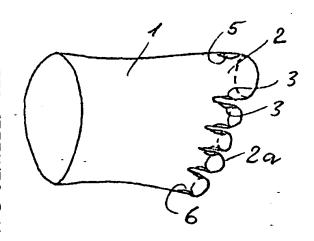
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SOCK OR STOCKING FOR THERAPEUTIC USE



(57) Abstract: The invention relates to a foot-shaped sock or stocking for therapeutic use, made of thin, flexible and preferably also elastic material. To the inner surface of the toe cavities of said foot-shaped sock or stocking are fastened a number of elastomeric, pad-like inserts that relieve pressure on the inner side of the toe. The elastomeric insert according to the invention are suitably made of a soft, almost viscous plastic, for instance of a known silicone-based gel type, said inserts being fastened on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable way. The sock or stocking itself is made of nylon or an equivalent thin and elastic textile, preferably of a type which has an appropriate permeability to vapour, and which occupies as little space and causes as little inconvenience as possible, so that the bandage can be worn under ordinary footwear.

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Sock or Stocking for Therapeutic Use.

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The invention is a sock or stocking for therapeutic use, more specifically as defined in the introduction to claim 1.

It is known that corns, bunions and related pressure sore problems on the feet can be treated with pressure-relieving dressings consisting of a soft elastomeric pad which is held in position over the affected point on the foot with the aid of an elastic bandage or a plaster. The exposed and often highly pressure-sensitive part of the foot is thus protected against direct external pressure and against the irritation which, for example, can be caused by friction against the shoe, or, in the case of a pressure sore on the inner side of a toe, by rubbing against the neighbouring toe. The elastomeric insert or pad is usually made of a soft, almost viscous plastic. This plastic, which, for example, can consist of a silicone-based gel or another appropriate elastomer, is characterised by being extremely soft and workable, and ensures an optimal relief of pressure via this property and alleviation at the point of tenderness. The insert is usually shaped (prefabricated) as a flat circular piece which is placed over the tender point and fixed with the aid of the bandage as specified above. The insert or pad is referred to below as a pad.

The known technique is usable for the treatment of a single bunion or a single pressure sore of limited physical extent, but in practice it is a problem that the bandage used to fix the pad is often very bulky, as a result of which the dressing itself can be a source of irritation and can, at worst, cause new pressure sores. The known treatments for relief of pressure are unsuitable for the prophylactic treatment of patients who are known to have a substantial risk of developing pressure sores on the feet, such as patients with diabetes, heart patients and patients with paralysis, because prophylactic use of the known forms of treatment will of its very nature assume a large number of individual dressings and pads on the foot at the same time, and this is of course not possible in practice without major inconvenience for the patient.

U.S. patent no. 5,823,195 describes a therapeutic stocking with two ankle inserts. The two ankle inserts protect the ankle and the area around it down to the heel against the formation of sores. The elastic stocking ensures an even pressure distribution over the relevant part of the foot. The ankle inserts are made of a silicone elastomer and are hydrophobic. For obvious reasons the therapeutic stocking is unsuitable for use in prophylactic treatment to prevent pressure sores between the toes. The ankle inserts are placed in the therapeutic stocking as loose inserts. In practice this is done by the patient first putting on the stockings, after which the inserts are placed in them. The procedure is laborious and means that many patients, for example those with restricted ability to move or with paralysis, will have difficulty completing the task without assistance.

The object of the invention was to devise an improved form of pressure-relieving bandage or dressing which, based on known forms of treatment using point-wise relief of pressure on particularly exposed areas of the foot, would enable simultaneous relief of pressure at a number

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of points or areas of the foot. An attempt was also made to find a solution which can be used in everyday life as normal preventive treatment for the patients at special risk discussed above, so that these patients' problems with pressure sores on the feet and between the toes can be prevented simply and effectively. The invention's pressure-relieving bandage must be easy to put on and take off, the bandage must be able to be worn discreetly under the clothing (under stockings or similar), and the bandage may not cause discomfort or other forms of inconvenience to patients. These and other benefits are achieved in the invention by equipping the dressing as specified in the characterising part of claim 1.

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The new element in the invention is that a number of elastomeric, pad-like inserts are fastened, opposite the area(s) of the foot on which pressure is to be relieved, on the inner side of the foot-shaped sock or stocking, which is appropriately made of thin flexible and mainly also elastic material (textile of natural or artificial material). With a single bandage, the patient can thus gain pressure relief in a single action at all points on the foot which are liable to the formation of sores (pressure sore problems) or which are tender or exposed to pressure for other reasons. The bandage is simple for the patient to apply, thanks to the textile material's elasticity and the bandage's foot-shaped form. The elastomeric inserts attached to the inner side of the bandage will immediately sit "correctly" in relation to the areas of the foot which are exposed to pressure when the bandage is pulled on, and in particular the pads which are to protect the inner sides of the toes and the outer sides of the joints are positioned correctly solely because of the bandage's "foot shape". During use, the bandage ensures that the pads are held in their correct relative positions and that the pads do not shift unintentionally relative to their various pressure points. The bandage's main use will be for prophylactic purposes.

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The invention's elastomeric inserts are suitably made of a soft, almost viscous plastic, for example a known silicone-based gel-like type. Alternatively, the insert can be made of foamed plastic, foam rubber, natural rubber or another appropriate material. The elastomeric inserts are fastened to the inner side of the bandage by thermal welding, sewing, adhesion or other appropriate method. The sock or stocking itself is made of NYLON or an equivalent thin and elastic textile, mainly of a type with a suitable permeability to water vapour and which takes as little space and causes as little inconvenience as possible so that the bandage can be worn under ordinary footwear (socks, stockings, shoes etc.) without inconveniencing the patient.

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In one preferred embodiment of the invention, the bandage is equipped with separate cavities for the individual toes, that is, cavities analogous to the "fingers" in a glove. The inner sides of these toe cavities carry elastomeric inserts dimensioned for therapeutic pressure relief on the inner sides of the toes, that is, in the spaces between the toes. Experience has shown that these areas of the feet are highly susceptible to the formation of pressure sores. The bandage makes it possible to relieve the pressure on the exposed areas in a very gentle and yet effective

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manner, without making the bandage bulky and uncomfortable to wear. The toe cavities are appropriately open at the ends, so that the bandage terminates at the toe's outer joint. In popular terms, the toe ends of the bandage are cut off. From the toes, the bandage extends backwards to about the middle of the forefoot. The bandage is thus shaped like a half-sock. In this embodiment the bandage is extremely comfortable for the patient to wear, and the price of manufacture for the bandage is the lowest possible.

Examples of preferred embodiments of the bandage according to the invention are given in claims 5-8. The bandage itself can be shaped like a full sock, a half sock or a knee-high stocking as required, and the elastomeric inserts can be freely placed in the bandage according to where there is a need for pressure relief. Claim 8 concerns an embodiment equipped with full foot lamina, that is, where the elastomeric insert almost forms an internal sole in the bandage. This form of therapeutic stocking is used with advantage by patients with fallen arches.

To increase the therapeutic effect of the bandage, the invention makes it possible to supplement the pressure-relieving effect with some form of medication. This requires the measures specified in claims 9 and 10, which consist of the elastomeric inserts containing a drug which is released successively to the patient during the treatment, either by diffusion, evaporation or otherwise dissolving. Under the invention the drug can be a hormone, an antibiotic e.g. for the healing of sores, a morphine preparation to treat pain in combination with the soothing effect of the pad, or other appropriate medication.

A more detailed description of the invention is now given in association with the drawings, of which

- Fig. 1 shows a forefoot bandage according to the invention with pressure pads inserted between the toes, viewed obliquely from the front, in use on a patient.
 - Fig. 2 The same separately, viewed obliquely from above.
 - Fig. 3 The forefoot bandage viewed directly from the front.
 - Fig. 4 A magnified section which shows a toe section of the bandage with associated pressure pads.
- 30 Fig. 5 The same in cross-section.
 - Fig. 6 The same in an embodiment with circular ring-shaped pressure pad which completely surrounds the toe.
 - Fig. 7 A stocking-shaped, knee-length bandage according to the invention viewed obliquely from the side.
- 35 Fig. 8 The underside of the same with the foot lamina insert marked.

In the embodiment shown in Figs. 1-5, the sock or stocking consists principally of an elastic bandage 1 in the shape of a "foot glove", designed to cover the forefoot from the outer joints of the toes to about the middle of the forefoot as shown. The bandage is called a forefoot sock.

The bandage, which is made of an elastic textile material (NYLON or equivalent), has separate

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"fingers" for the toes, that is, cavities 2 in which the toes fit when the stocking is put on. These "fingers" or cavities 2 are open at the ends 2a, so that the outer joints of the toes are not covered by the bandage. Experience shows that the outer joints seldom suffer pressure sores or similar problems.

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The bandage is equipped on the inner side with elastomeric inserts 3 at the points where pressure on the foot and the toes is to be relieved. In the embodiment shown there are several separate inserts 3 in the actual toe cavities 2, designed to relieve the pressure of the inner sides of the toes against each other. The inserts are shaped as circular or rectangular pads which are fastened to the inner side of the bandage by sewing, thermal welding or adhesion. Alternatively, the inserts on the toe cavities 2 can be ring-shaped (insert shown in 4) to completely encircle the toe when the bandage is put on (Fig. 6). Inserts placed opposite bunions, i.e. on the outer sides of the big and the little toes, can also be used in the forefoot stocking in question (inserts 5 and 6).

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Figs. 7 and 8 show the bandage in a knee-length embodiment 7, but still with separate cavities for the toes which are open at the ends 2. Apart from the toe inserts 3 already discussed, the knee-length stocking can be equipped with inserts 8 opposite the heel and opposite both ankle protuberances. In a special embodiment this knee-length stocking can also be equipped with a full foot lamina 9 of elastomeric material designed for therapeutic treatment of patients with fallen arches. In other embodiments not figured here, the bandage can be shaped like a short sock and fitted with inserts combined in various ways according to the patient's individual needs. The inserts can, as already discussed, contain a drug which is successively released during the treatment via the pad's direct contact with the skin.

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PATENT CLAIMS

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1. Sock or stocking for therapeutic use, where the therapeutic treatment consists essentially of a partial covering and relieving of pressure on particularly exposed points or areas of the foot, using a pressure-relieving pad of soft elastomeric material which is placed over the affected area of the foot and fixed with the aid of an elastic bandage which surrounds the foot or at least that

- 2. part of the foot containing the exposed (tender) point, and which surrounding bandage is comprised of an essentially foot-shaped sock or stocking 1, 7 made of thin flexible and mainly also elastic material (textile of natural or artificial fibres), characterised by the fastening of a number of elastomeric, pad-like inserts 3, 5, 6 to the inner surface of the toe cavities in the foot-shaped sock or stocking in order to relieve pressure on the inner sides of the toes.
- 2. Sock or stocking as defined in claim 1, characterised by the elastomeric inserts being made of a soft, almost viscous plastic, for example of a known silicone-based gel type, which inserts are fixed on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable manner.
- 3. Sock or stocking as defined in claim 1, characterised by the sock (1) or the stocking (7) itself being made of NYLON or an equivalent thin and elastic textile, mainly of a type which has an appropriate permeability to water vapour and which occupies as little space and causes as little inconvenience as possible.
- 4. Sock or stocking as defined in claims 1, 2 or 3, characterised by the bandage, i.e. the foot-shaped sock or stocking, being designed with separate cavities (2) for the individual toes (i.e., cavities analogous to the "fingers" in a glove), and the placing of elastomeric inserts (3) on the inner sides of these cavities designed for therapeutic relieving of pressure on tender points on the toes, mainly in the spaces between the toes.
 - 5. Sock or stocking as defined in claim 4, characterised by the toe cavities in question (2) being open at the ends (2a), the bandage terminating at the outer joints of the toes so that the outer joints of the toes with toenails protrude beyond the bandage (1), that elastomeric inserts are positioned between all toes, and mainly also opposite the bunions on the inner and outer sides of the forefoot, and that the bandage extends back to about the middle of the forefoot (Fig. 1).
 - 6. Sock or stocking as defined in claims 4 or 5, characterised by the elastomeric inserts (4) in the toe cavities (2) each being a circular, ring-shaped encircling of the toe in question.

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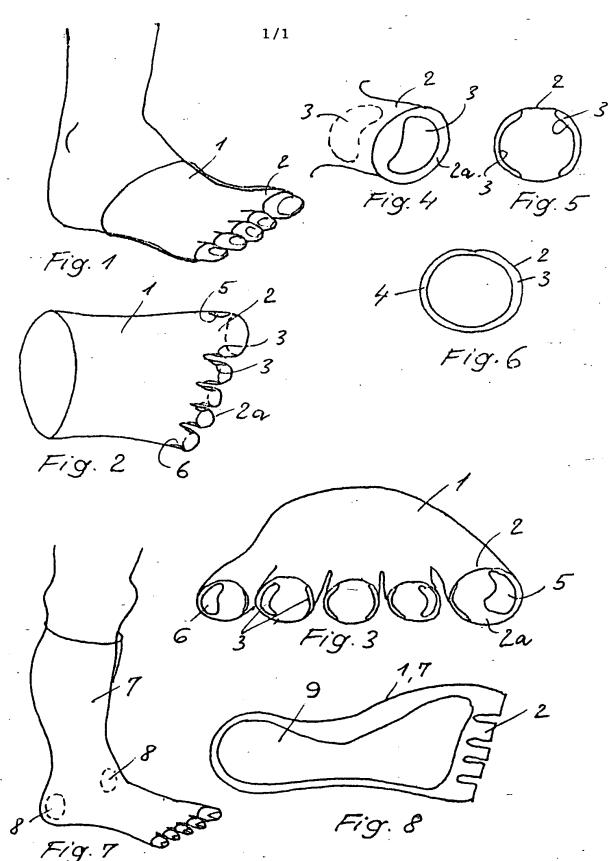
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- 7. Sock or stocking as defined in one or more of claims 4, 5 or 6, characterised by the bandage being prolonged backwards into an actual sock, so that the bandage both encircles the forefoot and the heel and that various inserts are placed in the sock in addition to the toe inserts (3) according to the patient's needs, which inserts can, for example, include: one or more inserts (8) opposite the heel, an insert for the entire length of the sole (lamina insert 9), and inserts opposite both ankle protuberances (inserts 8).
- 8. Sock or stocking as defined in one or more of claims 4-7, characterised by the bandage having an increased length, mainly with termination immediately below knee height, i.e., as a knee-length stocking (7).
- 9. Sock or stocking as defined in claims 1 and 2, characterised by the elastomeric inserts containing a drug which is successively released during the therapeutic treatment either by diffusion, evaporation or otherwise dissolving.
- 10. Sock or stocking as defined in claim 9, characterised by the drug in question being a hormone, an antibiotic e.g. to heal sores, a morphine preparation for the treatment of pain in combination with the soothing effect of the pad, or other medication appropriate to the purpose.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 00/00517

A. CLASSIFICATION OF SUBJECT MATTER IPC7: A61F 13/06 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SE,DK,FI,NO classes as above Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Citation of document, with indication, where appropriate, of the relevant passages Category* US 5497789 A (ZOOK), 12 March 1996 (12.03.96), 1-10 A abstract 1-10 FR 1176074 B1 (JUAN LESIUK), 3 April 1959 Α (03.04.59), figures 5,6, claim 1 1-10 JP 9099004 A (CHOYO KK)1997-07-15 (abstract) World P A atents Index (oneline). London, U.k:Derwent Publicat ions, Ltd: (retrieved on 2000-12-14). Retrieved from; EPO WPI Database. DW199725, Accession No.98-149073; 1-10 SE 464906 B (AB IE-KLINIKEN), 1 July 1991 (01.07.91), figure 1, abstract Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination special reason (as specified) document referring to an oral disclosure, use, exhibition or other being obvious to a person skilled in the art document published prior to the international filing date but later than "&" document member of the same patent family the priority date claimed Date of the actual completion of the international search Date of mailing of the international search report **2 0** -12- 2000 14 December 2000 Authorized officer Name and mailing address of the ISA: Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Ingrid Falk/js

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 00/00517

Category*	Citation of document, with indication, where appropriate, of the releva	nit passages	Relevant to claim N	ο.
A	US 5823195 A (SHOOK ET AL), 20 October 1998 (20.10.98), abstract		1-10	
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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International application No.

	nt document search report		Publication date		ent family nember(s)		Publication date
US	5497789	Α	12/03/96	NONE			
FR	1176074	B1	03/04/59	NONE			
SE	464906	В	01/07/91	SE	8903007	A	14/03/91
US	5823195	A	20/10/98	NONE			

Form PCT/ISA 210 (patent family annex) (July 1998)

PATENT COOPERAT TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA)		
19536 International application No.	International filing date (day/ma	onth/year)	Priority date (day/month/year)	·.a
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International Patent Classification (IPC) or national classification and IPC7			
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This international preliminary examination report has been p Authority and is transmitted to the applicant according to Ar	repared by this International Preliminary Examining ticle 36.			
2. This REPORT consists of a total of 3 sheets,	including this cover sheet.			
This report is also accompanied by ANNEXES, i.e., si been amended and are the basis for this report and/or (see Rule 70.16 and Section 607 of the Administrative	heets of the description, claims and/or drawings which have sheets containing rectifications made before this Authority Instructions under the PCT).			
These annexes consist of a total of sheets.				
3. This report contains indications relating to the following item	ns:			
I Basis of the report				
II Priority				
III Non-establishment of opinion with regard to no	velty, inventive step and industrial applicability			
IV Lack of unity of invention				
V Reasoned statement under Article 35(2) with recitations and explanations supporting such state	gard to novelty, inventive step or industrial applicability; ement			
VI Certain documents cited				
VII Certain defects in the international application				
VIII Certain observations on the international applic	ation			
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25.01.2001	19.12.2001			
Name and mailing address of the IPEA/SE	Authorized officer			
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S-102 42 STOCKHOLM PATOREG-S Facsimile No. 08-667 72 88	Ingrid Falk / MRO Telephone No. 08-782 25 00			
Form PCT/IPEA/409 (cover sheet) (January 1998)				



International application No.

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I. Basis of the report	
1. With regard to the elements of the international application:*	
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or 55.3). 3. With regard to any nucleotide and/or amino acid sequence dispreliminary examination was carried out on the basis of the sequence on tained in the international application in written form. filed together with the international application in compute furnished subsequently to this Authority in written form.	of (under Rule 48.3(b)). of international preliminary examination (under Rules 55.2 and/ closed in the international application, the international ence listing: ter readable form.
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4. The amendments have resulted in the cancellation of:	
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the drawings, sheet/fig	-
	dments had not been made, since they have been considered to go
 Replacement sheets which have been furnished to the receiving in this report as "originally filed" and are annexed to this repo and 70.17). 	Office in response to an invitation under Article 14 are referred to ort since they do not contain amendments (Rules 70.16
** Any replacement sheet containing such amendments must be re	ferred to under item I and annexed to this report.



International application No.

PCT/DK00/00517

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES NO
(15)	Claims Claims	1-10	YES
Inventive step (IS)	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES NO

2. Citations and explanations (Rule 70.7)

Cited documents:

- (1) US 5497789 A (ZOOK)
- (2) FR 1176074 B1 (JUAN LESIUK)
- (3) JP 9099004 A (CHOYO KK)
- (4) SE 464906 B (AB IE-KLINIKEN)
- (5) US 5823195 A (SHOOK ET AL)

The documents cited in the International Search Report represent background art.

The invention defined in claims 1-10 is not disclosed by any of these documents.

None of the cited documents gives any indication towards the claimed sock or stocking for therapeutic use. No relevant combination of the cited documents would lead a person skilled in the art to the invention defined in claims.

Therefore, the invention defined in claims 1-10 is novel and is considered to involve an inventive step. It is also considered to be industrially applicable.



RECORD CO

REQUEST

The undersigned requests that the present international application be processed

- For receiving Office use only -

PCT/DK 00/00517 International Application No.

> 19 SEPTEMBER, 2000

International Filing Date

Danish Patent and Trademark Office

iving Office and Promisenational Application

according to the Patent Cooperation Treaty.	Name of receiving Office and PCY international Application					
Litte has changed see 188	Applicant's or agent's sile reference (if desired) (12 characters maximum) 19536					
Box No. I TITLE OF INVENTION						
Sock or stocking for there	apeutical use 🗡					
Box No. II APPLICANT						
Name and address: (Family name followed by given name; for a designation. The address must include postal code and name of cou address indicated in this Box is the applicant's State (that is, country of residence is indicated below.)	Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)					
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Smedegade 30 DK-6950 Ringkøbing	Facsimile No.					
	Teleprinter No.					
State (that is, country) of nationality:	State (that is, country) of residence:					
DK	DK					
This person is applicant for the purposes of:	d States except the United States the States indicated in tates of America only the Supplemental Box					
Box No. III FURTHER APPLICANT(S) AND/OR (FURT	HER) INVENTOR(S)					
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) NIELSEN, Ludvig Nikolaj Torvegade 14 DK.6950 Ringkøbing inventor only (If this check-box is marked, do not fill in below.)						
State (that is, country) of nationality: DK	State (that is, country) of residence: DK					
This person is applicant	States except the United States the States indicated in the Supplemental Box					
Further applicants and/or (further) inventors are indicated o	n a continuation sheet.					
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The person identified below is hereby/has been appointed to act or of the applicant(s) before the competent International Authorities	a behalf agent common representative as:					
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MAGNUS JENSENS SUCCESSORS	1					
EUROPEAN PATENT ATTORNEYS	1					
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Address for correspondence: Mark this check-box where no space above is used instead to indicate a special address to wi	agent or common representative is/has been appointed and the hich correspondence should be sent.					



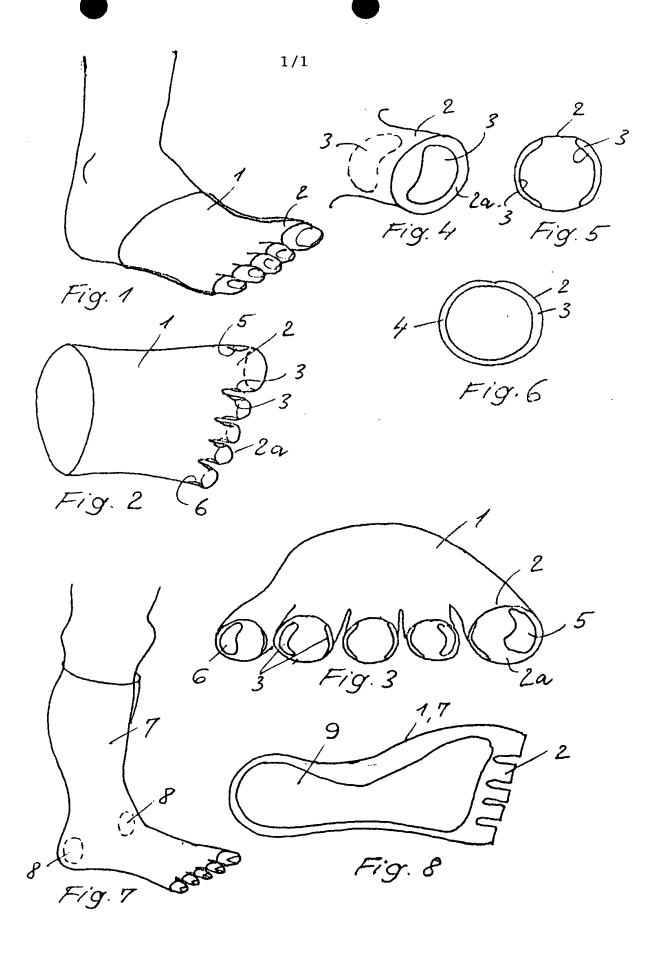
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designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant										
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	Sheet No.	3	
CLAIM		Furth	er prior

Box No. VI PRIORITY CL	AIM	Further prior	ority claims are indicated	in the Supplemental Box.			
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Convention for the Protection of in	augiriai i roperty jer mitel		led (Rule 4.10(b)(ii)). See S	Supplemental Box.			
Box No. VII INTERNATIO	DNAL SEARCHING AUT	THORITY					
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Opfindelsen angår en sok eller strømpe til terapeutisk brug, og nærmere bestemt af den i indledningen til krav 1 angivne art.

Det er kendt at behandle knyster og lignende tryksårsproblemer på fødderne med trykaflastende forbindinger af en type, som består af et blødt, elastomert polster, som fastholdes over det angrebne punkt på foden v hj af en elastisk bandage eller v hj af et plaster. På denne måde beskyttes det udsatte og ofte meget trykfølsomme område af foden mod direkte tryk udefra og mod den irritation, som eksempelvis friktionen mod fodtøjet kan give anledning til, eller –såfremt der er tale om et tryksår på indersiden af en tå- som gnidningen mod nabotåen kan forårsage. Det elastomere indlæg eller polster er sædvanligvis fremstillet af et blødt, nærmest viskost formstof. Dette formstof, som eksempelvis kan bestå af en silikonebaseret gel eller en anden til formålet egnet elastomer, udmærker sig ved at være extremt blødt og formbart, og sikrer qua denne egenskab en optimal trykaflastning og lindring i det ømme punkt. Indlægget er sædvanligvis formet (præfabrikeret) som en flad, cirkulær brik, som anbringes over det ømme punkt og fikseres v hj af bandagen som anført. Indlægget eller polstringen betegnes i det følgende som en pude.

Til behandling af en enkelt knyst eller et enkelt tryksår med begrænset fysisk udstrækning er den kendte teknik for så vidt anvendelig. Dog er det i praksis et problem, at den til fiksering af puden anvendte bandage ofte er meget omfangsrig, hvorved forbindingen i sig selv kan virke irriterende og i værste fald forårsage nye tryksår. Til profylaktisk behandling af de grupper af patienter, som man erfaringsmæssigt ved har stor risiko for at udvikle tryksår på fødderne, dette gælder bl a patienter med diabetes, hjertepatienter og patienter med lammelser, er de kendte behandlingsmidler til trykaflastning uegnede, idet en profylaktisk anvendelse af de kendte behandlingsmidler i sagens natur ville forudsætte brug af et stort antal enkeltforbindinger og trykpuder på foden samtidig, og dette er naturligvis ikke muligt i praksis uden stor gene for patienten.

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Til grund for opfindelsen ligger den opgave, at anvise en forbedret form for trykaflastende bandage eller forbinding, som med udgangspunkt i den kendte behandlingsform baseret på punktvis trykaflastning af særligt udsatte områder af foden muliggør en samtidig trykaflastning i flere punkter eller områder af foden samtidig. Der tilstræbes nærmere bestemt en løsning, som kan anvendes i dagligdagen som normal forebyggende behandling blandt andet af den ovenfor omtalte gruppe af særligt udsatte patienter, hvorved disse patienters problemer med tryksår på fødderne og mellem tæerne kan forebygges på en enkel og effektiv måde. Den trykaflastende bandage ifølge opfindelsen skal være let at tage af op på, bandagen skal kunne bæres diskret under beklædningen (under strømper eller lignende), og bandagen må ikke medføre ubehag eller andre former for gener for patienterne. Dette og andre mål opnås ifølge opfindelsen ved at indrette forbindingen som angivet i den kendetegnende del af krav 1.

Det nye ved opfindelsen består i, at den omsluttende bandage udgøres af en i hovedsagen fodformet sok eller strømpe, som er fremstillet af tyndt, fleksibelt og fortrinsvis også elastisk materiale (tekstilmateriale af natur- eller kunststof), og at der på indersiden af denne fodformede sok eller strømpe er fæstnet et antal elastomere, pudeagtige indlæg ud for det eller de områder af foden, som skal trykaflastes. Med en enkelt bandage kan patienten på denne måde på én gang opnå en trykaflastning i alle de punkter af foden, som er udsat for sårdannelse (tryksårsproblemer) eller som er ømme eller trykudsatte af anden årsag. Bandagen er let at iføre sig for patienten takket være tekstilmaterialets elasticitet og bandagens fodtilpassede form. De elastomere indlæg, som er fastsiddende på indersiden af bandagen, vil umiddelbart komme til at sidde "rigtigt" i forhold til de

trykudsatte områder af foden, når bandagen trækkes på, og specielt de puder, som skal beskytte indersiderne af tæerne og ydersiderne af knoerne, positioneres korrekt alene som følge af bandagens "fodform". Under brugen sikrer bandage, at puderne holdes i korrekt indbyrdes stilling og at der ikke sker en utilsigtet forskydning i forhold til pudernes resp. trykpunkter. Fortrinsvis benyttes bandagen profylaktisk.

Formålstjenligt er de elastomere indlæg ifølge opfindelsen fremstillet af et blødt, nærmest viskost formstof, eksempelvis af en kendt silikonebaseret, gelagtig type. Alternativt kan indlægget være fremstillet af opskummet formstof, skumgummi, naturgummi eller et andet til formålet egnet materiale. De elastomere indlæg er fæstnet til indersiden af bandagen ved termosvejsning, syning, klæbning eller på anden egnet måde. Sokken eller strømpen i sig selv er fremstillet af NYLON eller et tilsvarende tyndt og elastisk tekstilprodukt, fortrinsvis af en art, som har en passende permeabilitet for vanddamp, og som fylder og generer mindst muligt, således at bandagen kan bæres under almindelig fodbeklædning (sokker, strømper, fodtøj, etc) uden gene for patienten.

I en foretrukken udførelsesform ifølge opfindelsen er bandagen indrettet med indbyrdes adskilte hulrum for de enkelte tæer, dvs hulrum, som er analoge med "fingrene" i en fingerhandske. På indersiden af disse tå-hulrum er der placeret elastomere indlæg beregnet til terapeutisk trykaflastning af tæernes indersider, dvs i mellemrummene mellem tæerne. Disse områder af fødderne er erfaringsmæssigt meget udsatte for tryksårsdannelser. Bandagen gør det muligt at trykaflaste de udsatte områder på en meget skånsom og alligevel effektiv måde, og uden at bandagen derved bliver voluminøs og ubekvem at bære. Formålstjenligt er tå-hulrummene åbne i enderne, således at bandagen er afsluttet ved tæernes yderled. Populært sagt er bandagens tåender klippet af. Fra tæerne strækker bandagen sig bagud på foden til omtrent midt på forfoden. Der er altså tale om en bandage i halvstrømpeform. Bandagen bliver i denne udførelsesform særlig bekvem for patienten at bære, ligesom fremstillingsprisen for bandage bliver mindst mulig.

Eksempler på foretrukne udførelsesformer for bandagen ifølge opfindelsen er angivet i kravene 5 til 8. Selve bandagen kan alt efter behovet have form som en helsok, en halvsok eller en knæstrømpe, og de elastomere indlæg kan placeres frit i bandagen alt efter, hvor der er behov for trykaflastning. Krav 8 omhandler en udførelsesform forsynet med fuld fodplade, dvs hvor det elastomere indlæg nærmest danner en indvendig sål i bandagen. Denne form for terapeutisk strømpe benyttes med fordel af patienter med mellemfodssynkning.

For at intensivere den terapeutiske virkning af bandagen er det ifølge opfindelse muligt at supplere den trykaflastende effekt med en vis form for medicinering. Hertil tjener de i kravene 9 og 10 anførte foranstaltninger, som består i, at de elastomere indlæg indeholder et farmaka, som afgives successivt til patienten under behandlingen, enten ved diffusion, afdampning eller afkvældning. Som farmakon kan der ifølge opfindelsen være tale om et hormonmiddel, et antibiotikum eksempelvis til sårheling, et morfinpræparat til smertebehandling i kombination med trykpudens lindrende virkning, eller et andet til formålet egnet medikament.

Opfindelsen skal forklares nærmere i forbindelse med tegningen, hvor

- fig. 1 viser en forfodsbandage ifølge opfindelsen med trykpuder indsat mellem tæerne, set skråt forfra i anvendelse på en patient,
 - fig. 2 Samme vist separat, set skråt ovenfra,
 - fig. 3 Forfodsbandagen set lige forfra,

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- fig. 4 et forstørret udsnit, som viser en tå-del af bandagen med tilhørende trykpuder,
- fig. 5 samme vist i tværsnit,

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- fig. 6 samme vist i en udførelsesform med cirkulær, ringformet trykpude, som omslutter tåen helt,
- fig. 7 en strømpeformet, knælang bandage ifølge opfindelsen, set skråt fra siden, og
- fig. 8 undersiden af samme vist med markeret fodpladeindlæg.

I den på tegningens fig. 1 - 5 viste udførelsesform består sokken eller strømpen i det væsentlige af en elastisk bandage 1 formet som en "fod-handske" og beregnet til at dække forfoden fra tæernes yderled til omtrent midt på forfoden som vist. Bandagen benævnes en forfodsstrømpe. Bandagen, som er fremstillet af et elastisk tekstilmateriale (nylon eller tilsvarende), er formet med adskilte "fingre" for tæerne, dvs hulrum 2, hvori tæerne passer ind når strømpen tages på. Disse "fingre" eller hulrum 2 er åbne i enderne 2a, således at tæernes yderled holdes frie af bandagen. Yderleddene er erfaringsmæssigt sjældent udsatte for tryksårsdannelser eller lignende problemer.

- Bandagen er på indersiden forsynet med elastomere indlæg 3 i de punkter, hvor foden og tæerne skal trykaflastes. I den viste udførelsesform findes der et antal indbyrdes adskilte indlæg 3 i selve tå-hulrummene 2 beregnet til trykaflastning af tæernes mod hinanden vendende indersider. Indlæggene har form som cirkulære eller rektangulære puder, der er fæstnet til indersiden af bandagen ved syning, termosvejsning eller klæbning. Alternativt kan indlæggene i tåhulrummene 2 være ringformede (indlæg angivet med 4) for hel omslutning af tåen, når bandagen tages på, se fig. 6. Også indlæg placeret ud for knysterne, dvs på ydersiden af storetåen og lilletåen, kan komme på tale ved den omhandlede forfodsstrømpe (indlæg angivet med 5 og 6).
- I fig. 7 og 8 er bandagen vist i en udførelsesform som knæstrømpe 7, dog stadig med adskilte og i enderne åbne hulrum 2 for tæerne. Knæstrømpen kan, foruden de allerede omtalte tåindlæg 3, være forsynet med indlæg 8 ud for hælpartiet og ud for begge ankelknoer. I en særlig udgave kan denne knæstrømpe endvidere være forsynet med en fuld fodplade 9 af elastomert materiale beregnet til terapeutisk behandling af patienter med mellemfodsnedsænkning. I andre ikke viste udførelsesformer kan bandagen have form som en kort sok, og bestykningen med indlæg kan kombineres på forskellig måde, alt efter patientens individuelle behov. Indlæggene kan, som allerede omtalt, indeholde et farmaka, som afgives successivt under behandlingen ved trykpudens direkte kontakt med huden.
- Opfindelsen er ikke begrænset til de på tegningen viste og ovenfor beskrevne udførelsesformer.

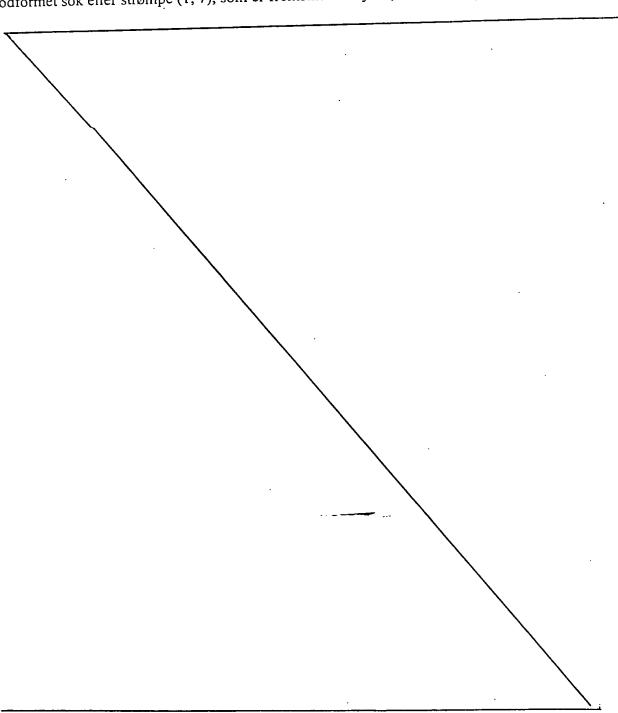
 Andre materialekombinationer og andre detailudformninger for den terapeutiske sok eller strømpe er tænkelig indenfor rammerne af denne opfindelse, ligesom princippet i sokken eller strømpen kan tænkes anvendt i andre terapeutiske sammenhænge end lige netop den ovenfor beskrevne.

 Eksempelvis er en anvendelse af selve princippet i opfindelsen tænkelig også til en terapeutisk handske, albuebeskytter eller eksempelvis en knæbeskytter.

PATENTKRAV

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1. Sok eller strømpe til terapeutisk brug, hvor den terapeutiske behandling i det væsentlige består i en partiel tildækning og trykaflastning af særligt udsatte punkter eller områder af foden, hvorunder der benyttes en trykaflastende pude af blødt, elastomert materiale, som placeres over det pågældende område af foden og som fikseres v hj af et plaster eller en elastisk bandage (forbinding), som omslutter foden eller en tå på denne, afhængig af, hvor det udsatte (ømme) punkt befinder sig, kendetegnet ved, at den omsluttende bandage udgøres af en i hovedsagen fodformet sok eller strømpe (1, 7), som er fremstillet af tyndt, fleksibelt og fortrinsvis også elastisk



materiale (tekstilmateriale af natur- eller kunstfibre), og på hvis inderside der er fæstnet et antal elastomere, pudelignende indlæg (3, 4, 5, 6, 8) ud for det eller de områder af foden, som skal trykaflastes.

- 2. Sok eller strømpe ifølge krav 1, kendet egnet ved, at de elastomere indlæg er fremstillet af et blødt, nærmest viskost formstof, eksempelvis af en kendt silikonebaseret gel-type, hvilke indlæg er fastgjort på indersiden af bandagen ved termosvejsning, syning, klæbning eller på anden egnet måde.
- 3. Sok eller strømpe ifølge krav 1, kendetegnet ved, at sokken (1) eller strømpen (7) i sig selv er fremstillet af NYLON eller et tilsvarende tyndt og elastisk tekstilprodukt, fortrinsvis af en art, som har en passende permeabilitet for vanddamp, og som fylder og generer mindst muligt, således at bandagen kan bæres under almindelig fodbeklædning (sokker, strømper, fodtøj, etc) uden væsentlig gene for patienten.
- 4. Sok eller strømpe ifølge krav 1, 2 eller 3, kendetegnet ved, at bandagen, dvs den fodformede sok eller strømpe, er udformet med indbyrdes adskilte hulrum (2) for de enkelte tæer (dvs hulrum, som er analoge med "fingrene" i en fingerhandske), og at der på indersiden af disse tåhulrum er anbragt elastomere indlæg (3) beregnet til terapeutisk trykaflastning af ømme punkter på tæerne, fortrinsvis i mellemrummene mellem tæerne.
 - 5. Sok eller strømpe ifølge krav 4, kendet egnet ved, at de omtalte tå-hulrum (2) er åbne i enderne (2a), idet bandagen er afsluttet ved tæernes yderled, således at tå-yderleddene med tåneglene stikker udenfor bandagen (1), at der er anbragt elastomere indlæg mellem alle tæer, samt fortrinsvis også ud for knysterne på indersiden og ydersiden af forfoden, og at bandagen strækker sig bagud til omtrent midt på forfoden (fig. 1).

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- 6. Sok eller strømpe ifølge krav 4 eller 5, kendet egnet ved, at de elastomere indlæg (4) i tå-hulrummene (2) hver for sig danner en cirkulær, ringformet omslutning af den pågældende tå.
- 7. Sok eller strømpe ifølge et eller flere af kravene 4, 5 eller 6, kendet egnet ved, at bandagen er forlænget bagud til en egentlig sok, således at bandagen både omslutter forfoden og hælen, og at der foruden tå-indlæggene (3) er placeret forskellige indlæg i sokken alt efter patientens behov, hvilke indlæg eksempelvis kan omfatte: et eller flere indlæg (8) ud for hælpartiet, et indlæg i hele fodundersidens udstrækning (trædepladeindlæg 9), og indlæg ud for begge ankelknoer (indlæg 8).
 - 8. Sok eller strømpe ifølge et eller flere af kravene 4 7, kendetegnet ved, at bandagen har forøget længde, fortrinsvis med afslutning umidelbart under knæhøjde, dvs som en knæstrømpe (7).
- 9. Sok eller strømpe ifølge krav 1 og 2, kendet egnet ved, at de elastomere indlæg indeholder et farmaka, som afgives successivt under den terapeutiske behandling enten ved diffusion, afdampning eller afkvældning.
- 10. Sok eller strømpe ifølge krav 9, kendet egnet ved, at det omtalte farmakon kan være et hormonmiddel, et antibiotikum eksempelvis til sårheling, et morfinpræparat til smertebehandling i kombination med trykpudens lindrende virkning, eller et andet til formålet egnet medikament.



Sok eller strømpe til terapeutisk brug

Opfindelsen angår en sok eller strømpe til terapeutisk brug, hvor behandlingen består i en partiel tildækning og trykaflastning af særligt udsatte punkter eller områder af foden, hvorunder der benyttes en trykaflastende pude af blødt, elastomert materiale, som placeres over det pågældende område af foden og fikseres v hj af et plaster eller en bandage, som omslutter foden eller en tå på denne, afhængig af, hvor det udsatte (ømme) område befinder sig.

Det nye ved opfindelsen består i, at den omsluttende bandage udgøres af en i hovedsagen fodformet sok eller strømpe, som er fremstillet af tyndt, fleksibelt og fortrinsvis også elastisk materiale (tekstilmateriale af natur- eller kunststof), og at der på indersiden af denne fodformede sok eller strømpe er fæstnet et antal elastomere, pudelignende indlæg ud for det eller de områder af foden, som skal trykaflastes.

Formålstjenligt er de elastomere indlæg ifølge opfindelsen fremstillet af et blødt, nærmest viskost formstof, eksempelvis af en kendt silikonebaseret gel, som er fastgjort på indersiden af bandagen ved termosvejsning, syning, klæbning eller på anden egnet måde. Sokken eller strømpen i sig selv er fremstillet af Nylon eller et tilsvarende tyndt og elastisk tekstilprodukt, fortrinsvis af en art, som har en passende permeabilitet for vanddamp, og som fylder og generer mindst muligt, således at bandagen kan bæres under almindelig fodbeklædning (sokker, strømper, fodtøj, etc) uden væsentlig ubehag for patienten.